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TITLE: Smart Adaptive Socket to Improve Fit and Relieve Pain in Wounded Warriors

PRINCIPAL INVESTIGATOR: Dr. David Boone

CONTRACTING ORGANIZATION: Orthocare Innovations LLC
                             Edmonds, WA 98020

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               Fort Detrick, Maryland 21702-5012

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PI: Dr. David Alan Boone
Author: Aizen Ulric

E-Mail: dboone@orthocareinnovations.com ; aulric@orthocareinnovations.com

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Orthocare Innovations
123 2nd Ave S, Ste. 220
Edmonds WA, 98020

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
Enter a brief (approximately 200 words) unclassified summary of the most significant finding during the research period.

A modular attachment to the vacuum pump was developed to allow the system to control both the volume elements and the socket vacuum. The design and fabrication of the liner were refined as was the design of the liner to socket connection interface. The control algorithm was also improved and expanded. IRB approval for the clinical trial has progressed.

15. SUBJECT TERMS
Volume compensation, Viscoelastic, Vacuum pump, Liner, Prosthetic socket interface, Dynamic segmental volume control, Wireless connection, Pressure control system.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
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Prescribed by ANSI Std. Z39.18

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INTRODUCTION:

A prosthetic socket is the physical connection between the user's body and the prosthesis. The functionality and comfort of the prosthesis is to a great degree determined by the intimacy of this connection. Fluctuations in body volume lead to changes in socket fit that negatively influence limb health. These volume changes can be due to the long-term effects of pharmaceuticals, weight gain, or weight loss. Limb volume can also decrease quite noticeably (as much as 11%) throughout the day due to the venous return of fluid out of the tissue caused by the forces of ambulation. This project directly addresses the prevalent and unmet need of prosthetic users for a socket that accommodates a changing residual limb volume while maintaining comfort and fit. We will develop and complete preliminary real world human wear test validation for a smart adaptive socket system (SASS) that controls limb loading and socket fit through dynamic segmental volume control. The system includes a liner with three distinct viscoelastic foam volume elements and a silent relatively mild vacuum suspension system, which is also used to control the volume in the liner by evacuating and compressing the foam elements. This system provides improved stability, proprioception, and reduced abrasion by eliminating voids and excess pressure in the socket.

KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

> **SASS –** *Smart Adaptive Socket System including a liner and a vacuum pump.*
> **Volume Element –** *A viscoelastic foam element that built into the liner that can be expanded or compressed to compensate for volume changes in the limb.*
> **Viscoelastic Foam –** *Foam that has both viscous and elastic properties, which vary with strain, strain rate, and frequency.*
> **Distal –** *A the far end, distant from the center of the body.*

ACCOMPLISHMENTS: .

What were the major goals of the project?
Aim 1: Design SASS Systems
1.1 Optimal adaptive element layout
1.2 Refine material selection
1.2.a Optimize for: thermal dependence
1.2.b Maximum patient comfort
1.2.c improve response times for changes in volume

1.2.d Maximize range of compression region 2 the elastic buckling plateau
1.3 Refine and implement adaptive control algorithm
1.3.a Large posterior element maintains a even mean pressure (snugness)
1.3.b stabilizing element to reduce coronal plane moments
1.3.c Distal element: Maintain tolerable contact - indicate insufficient support of other 2 elements
1.3.d Manual mode
1.3.e On board pressure transducer for each element
1.3.f Smart Pyr sensor
1.3.g 'Sport' vs 'Comfort' mode

Aim 2: Clinical feedback development trial
2.1 Recruit 15 individuals with war-related limb loss
2.2 Build prototype liners with 3 VE elements with discrete volume control
2.3 Long term use testing

What was accomplished under these goals?

1. Major Activities: The design of the liner was finalized and the manufacturing process was refined. An interface between the volume elements and the vacuum pump was iteratively redesigned. Modifications to the vacuum pump were developed to increase functionality. The control algorithm was further refined. A protocol for the clinical trial was designed.

2. Specific Objectives: Aim 1: Additions to the mechanical and electrical design of the pump and the mechanical design of the pump liner connection. The creation of a new prototype. Aim 1.1: Refining the liner fabrication method and finalizing the foam element thickness through the creation of prototype liners. Aim 1.3: The adaptive control algorithm was refined. Aim 2: A protocol for clinical trials was developed.

3. Results:

3.1 Overview:

   a. *Liner Design and Fabrication:* Volume element shape and thickness was finalized and the method of fabrication was modified to allow for consistency. Material was selected for the liner's fabric cover. Fabrication steps and instructions were developed.

   b. *Liner to Socket Interface Design:* An interface was designed to allow for an easy connection between the liner and the vacuum pump. The attach valve in the interface was iteratively redesigned. Connection options for the distal volume element were investigated and refined.

   c. *Vacuum Pump Design:* A backpack attachment to pump manifold was designed and manufactured to allow pump control to switch between the socket and the liner. Electrical modifications were designed and implemented to achieve the same purpose.

   d. *Control Algorithm Design:* The control algorithm was further refined. Further development was completed on the mobile user interface.

3.2 Discussion of Results:

   a. *Liner Design and Fabrication:*
   A couple modifications were made to finalize the liner design and the fabrication process was developed. The volume element thickness requirements were further investigated and the design was updated. Initially, a thickness of 20mm was chosen based on some rough calculations of the required thickness for 11% volume accommodation. In order to refine the thickness requirement solid models were made of the volume elements and the surface area of each element was accurately determined (Figure 1). Additionally further research was done into average residual limb volumes and volume fluctuations. It was found that the average residual transtibial limb has a volume of

4282 cubic centimeters in the socket, which corresponds to a surface area of 377 square centimeters. The combined surface area of the medial and posterior volume elements is 211 square centimeters. The distal element was not included as it is not responsible for volume accommodation. If fact compressing the distal element may have an inverse effect on volume accommodation because it would allow the residual limb to sink further into the socket, which is roughly conical. Thus, with a surface area of 211 square centimeters to achieve 11% volume accommodation would require 20 centimeters of thickness change in the volume elements. Since the functional range of the foam is a little more than 50% of its thickness the volume elements would need to be 40 centimeters thick. However, it was also found that the average prosthesis user makes a daily adjustment of 3 2-ply socks. A single ply sock has a thickness of 0.4 centimeters, so an 8-ply volume adjustment, which is slightly more than the average daily adjustment, requires volume elements with a thickness of 11.5 centimeters. If the volume elements are too thick it drastically increases the difficulty of donning the liner. Therefore, a thickness of 11.5 centimeters was chosen. This should be sufficient for the majority users making of daily adjustments and it significantly improves the evacuation rate.

Figure 1 – Solid models of the medial and posterior volume elements 40mm thick (left pair) 11.5mm thick (right pair). The posterior elements (on the right in each pair) display the new curved shape.

The shape of the posterior volume element was modified to prevent buckling of the silicone covering and reduce residual stress in the foam (Figure 1). It was found that the previous distal element was insufficiently curved to match the curvature of the leg. When the foam was forced to conform to the shape of the leg this led to buckling in the inside surface of the liner. The uneven surface suggests an uneven pressure distribution, which may be uncomfortable for the user. In order to avoid this the shape of the distal element was modified to incorporate more curvature in a relaxed state.

The other addition to the liner design was the testing and selection of a material for the fabric cover. A fabric cover for the liner was selected to increase durability and ease of donning. Selection was based on isotropic elasticity, silicon permeability, and silicon adhesion.

Isotropic elasticity allows the fabric to provide vertical support to the liner while maintaining circumferential elasticity for ease of donning and comfort. Three materials with a circumferential elasticity of at least 200% and at least 1.2 times that of their vertical elasticity were chosen for further testing. Additionally, tests of silicone permeability and adhesion were conducted using 2 by 4 squares of the different fabric options. The results are summarized in Table 1.

Table 1 – Fabric liner cover materials properties

Material	Vertical Elasticity	Circumferential Elasticity	Silicon Permeability	Silicon Adhesion
Nylon Lycra	217%	266%	Very High	Moderate
Spandura Lycra	175%	210%	Low (on one side)	Good
Super Stretch Spandex	168%	242%	High	Moderate

It was found that good adhesion and limited permeability could be achieved with the Spandura Lycra if liquid silicon was applied to the loose woven (fuzzy) side of the material. Unlike the other two materials the Spandura Lycra did not exhibit debonding when stretched to elongations greater then 150%. The material selection was made and a new prototype was fabricated with a Spandura Lycra cover.

In the first year fabrication involved sandwiching the volume elements between two premade thin silicone liners. Several modifications were made to the fabrication process to improve functionality, decrease weight and increase the consistency of the finished product.

In the current procedure the distal and medial volume elements are connected with tubing and encased in very thin silicon sheets. This method provides a number of benefits. It prevents liquid silicon from permeating the foam in later steps and decreasing its functional volume. The seal around the volume elements and the placement of the tubing can be tested at this stage in the process where it is much easier to fix any problems. The volume elements can be kept in an evacuated state during fabrication, which prevents wrinkling in the liner when the volume elements are evacuated during use. Also, it is likely that when this project is commercialized the liners will be injection molded and it will be necessary to encase the volume elements to prevent their being saturated with liquid silicone.

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Figure 2 – Pictures from the liner fabrication process ordered sequentially left to right top to bottom

In order to simplify fabrication and ensure consistency in the finished liners templates and cutting instructions were developed for the foam volume elements. Previously paper patterns were used to mark the shape for the initial cut but most of the shaping was done by hand, which was time consuming and allowed for significant variations between volume elements. In the process of creating solid models (Figure 1) of the volume elements cutting operations were performed on the representation of a block to mimic the process of cutting the shape out of foam. The profiles used for each cut were then printed and used to make solid plastic templates (Figure 3). Cutting instructions were defined for using these templates and a reciprocating saw to sequentially shape each volume element out of foam blocks. The final step of smoothing the edges is still done by hand but does not have a significant impact on the final shape. The process is significantly faster, with the time required to shape the distal element reduced by more than half.

Figure 3 – A template for cutting the distal volume element

A third modification to the fabrication procedure reduced the weight and thickness of the final liner. The current process involves pre-coating the inside of the fabric cover with silicone and using it as the outer layer which was previously a premade silicone liner. This also significantly reduces the cost of liner fabrication, which was primarily governed by the cost of the thin silicone liners. In addition pre-coating the fabric prevents the liquid silicone from getting on the outside of the liner as it is compressed under vacuum.

Further steps were added for the attachment of the distal connection point. A mold for the distal umbrella overlay was designed and printed. A threaded tube was screwed into the umbrella and used to attach it to the mold. Then the mold was filled with liquid adhesive and the fabric-covered liner (on the leg mold) was attached to the top with the airflow tube from the liner going through the threaded tube. Overflow adhesive was removed and the assembly was allowed to set. The umbrella once attached provides a secure attachment point for the pin and a rout for airflow from the volume elements in the liner through the pin to the socket.
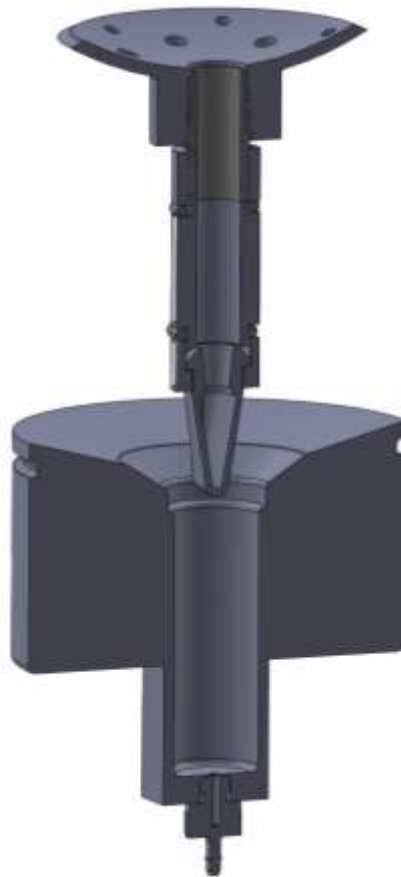
b. *Liner to Socket Interface Design:*

Figure 4 – A sectioned view of the solid model of both halves of the liner to socket interface.

The components of the liner socket interface were designed to allow the user to easily connect the volume elements in the liner to the vacuum pump system while donning their socket. The design was complicated by the natural pistoning of the residual limb in the socket during use and the need to maintain a secure connection without fixing the liner to the socket, which would cause localized forces on the residual limb. Finally, it was necessary that the liner side of the connection automatically seal upon removing the liner from the socket, so that a vacuum can be maintained in the volume elements after they are disconnected from the vacuum pump system. This will allow the user to evacuate their liner before putting it on. Having the liner hold its evacuated and compressed state will make the donning process significantly easier.

To achieve these requirements a distal pin and its complementary socket interface were designed (Figure 4). The pin screws into the distal umbrella on the liner and connects to the tube coming from the volume elements. On the end of the pin there is a normally closed valve, which seals the connection to the volume elements when the liner is removed from the socket, and around the outside of the pin there are two O-rings, which provide the seal. Placing the O-rings around the base of the pin allows the pin to move up and down in the cylindrical hole of the socket interface without breaking the seal.

The valve at the end of the pin was iteratively redesigned. Initially a Schrader valve was used. However, the Schrader valve on the end of the pin had a very limited vertical range between open and closed which would cause it to accidently close as the engagement of liner in the socket varied. In order to maintain an open connection without restricting vertical movement a custom valve was designed. The new valve can be described as an inverse duckbill. It is a rubber valve, which is normally closed but will be deformed into an open state by pushing it into a cylindrical hole. The inverse duckbill valve, unlike the Schrader valve, is also oriented so that when the volume elements are evacuated the force of atmospheric air pressure on the valve work to keep it closed instead of pushing it to open.

Figure 4 – Three valve prototype designs from the first design iteration (left) a soft valve showing tearing as it opens (middle) and a winged valve not opening (right).

Because the valve design is novel it was uncertain how changes in shape would affect the functionality. The initial design focused heavily on the incorporation of wings to use the pressure of the hole walls to induce a flat to cylindrical deformation. However, there were concerns that the wings would fold the wrong way or provide insufficient force to open the valve. Various designs were created to test the effects of giving either a convex or concave curve to the external walls with the intention of predisposing the wings to bend in the correct direction to open the distal slit (Figure 4). Since the functionality of the valve also depends on the stiffness of its material one of the designs was chosen to have prototypes made with a 40, 50, and 60 Shore A hardness. It was found that the wings were only effective for materials with high stiffness's and regardless of wall curvature they had a tendency to bend in the wrong direction. The softer valves also had a tendency to tear at the edge of the slit when opened (Figure 4) but the harder valves took longer to close after being removed from the hole. The simple cylindrical valve without wings was effective and was selected as the best choice. However, the prototype was tapered out towards the end and was difficult to insert into the hole. The un-tapered valves performed the best for insertion.

Figure 5 – The most recent valve prototypes (left), the shorter of which is being opened by the cylinder (right)

A second iteration of prototypes was created expanding on the cylindrical design (Figure 5) and Shore A hardnesses of 60, 70, and 85. The simplicity of the cylindrical design also allowed the valve designs to be shortened which will extend its range and make it sturdier and different lengths were tested. The final valve will most likely need to be made out of a different material, which will be possible when the valve is being molded instead of 3D printed. Since it was found that the lower hardness materials had a faster reaction time but were less durable using a different material with a balance between these two design factors will be necessary for the final valve.

The medial and posterior volume elements are attached to the Schroder valve. The distal volume element does not need to be compressed to facilitate donning nor does it directly affect the fit of the socket to the residual limb, as volume change in the residual limb is predominantly circumferential. Instead it provides support and comfort at the distal end of the limb. This is a sensitive area as the

end of the amputated bone can easily damage the surrounding tissue if it is used to carry too much of the weight bearing load. The distal foam element is used to apply a soft distributed pressure that will yield under high pressure. Initially, the design has the distal element connected to the atmosphere via a check valve and a parallel restrictor to allow it to compress under loading but expand slowly to maintain contact with the limb. However, the addition of a parallel line to the connection interface destroyed the radial agnosticism of the pin to hole connection complicating the donning process and decreasing the stability of the connection. The current design instead contains a number of radially symmetrical holes connecting the distal element to the socket volume. This is a elegantly simple design that causes the system to incidentally compress the distal element when the user is active and the vacuum in the socket is increased allowing the residual limb to seat more fully in the socket.

c. *Vacuum Pump Design:*

A backpack attachment to the pump manifold was designed to allow the system to switch between control of the liner volume elements and the socket (Figure 6). Switching between the socket and the liner allows the same vacuum pump hardware and electronics to be used with both components, drastically reducing the size and cost of the system. Keeping the backpack as a separate optional component from the main manifold also allows the vacuum pump to be individually viable. The backpack contains three barbs for connecting to the socket, the liner, and the vacuum pump, and a 3-way solenoid valve to control switching between the connections. The solenoid valve is connected to the electrical board so it can be controlled by the firmware. Implementing the manifold modifications as a backpack keeps the design modular allowing the vacuum pump and the liner to be used individually or combined.
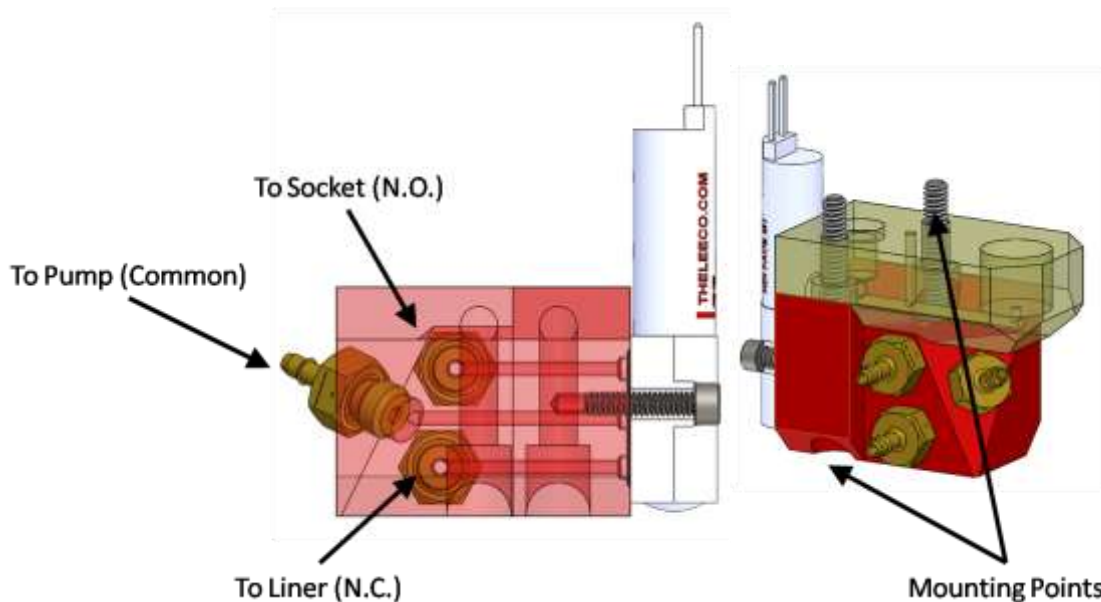
Figure 6 – The new backpack attachment mounted on the pump manifold.

The backpack is attached using the holes already in the pump manifold with slightly longer screws. The design is relatively light and compact and is implemented internal to the housing making the unit streamlined and attractive to the user.

The backpack went through 2 design iterations. In the final design the clearance between the internal passages has been increased and one of the barbs has been mounted on a diagonal. Putting the barb on a diagonal was necessary to reduce hose kink between manifold 2 and manifold 3.
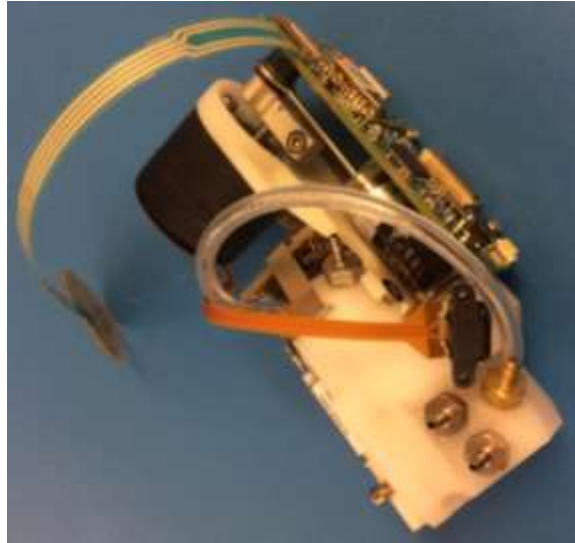
Figure 7 – A prototype with the new backpack attachment mounted on the pump manifold.

A modular addition to the electrical elements of the pump was also designed, incorporating a second 3-way solenoid valve and a power regulator and switching transistor to control the valve. The valve is used to switch the connection from the pump between the socket and the volume elements.

Power for 2nd valve is accessable at the positive motor terminal.

PUMP MOTOR

Maybird Main PCB Assembly (65135)

MAYBIRD BATTERY

Black
Red
White

P1 J3   J4
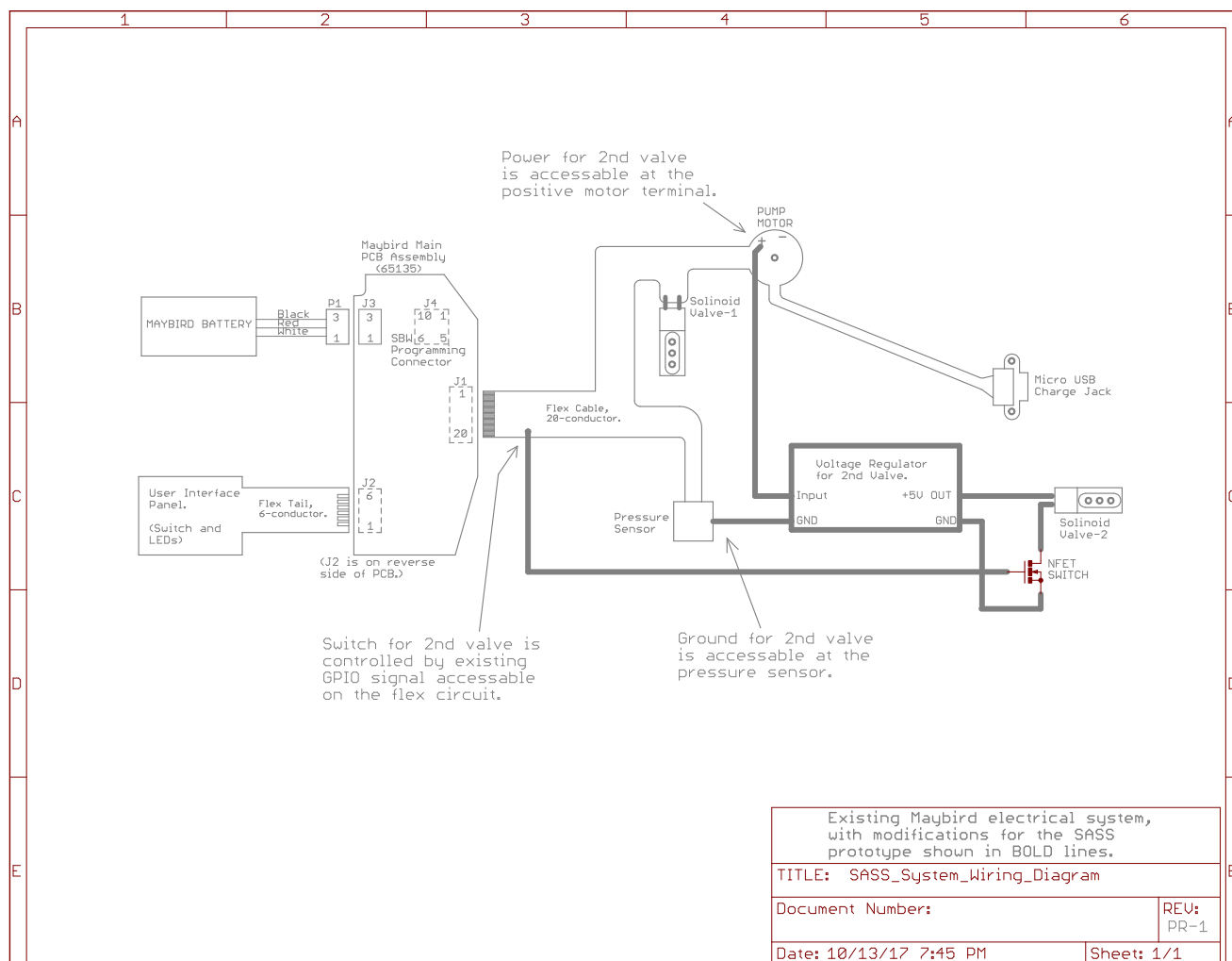3   3   10 1
1   1   SBW 6 5
        Programming
        Connector

Solinoid Valve-1

Micro USB Charge Jack

J1
1

20

Flex Cable, 20-conductor.

Voltage Regulator for 2nd Valve.
Input   +5V OUT
GND   GND

Solinoid Valve-2

User Interface Panel.

(Switch and LEDs)

Flex Tail, 6-conductor.

J2
6

1

Pressure Sensor

NFET SWITCH

(J2 is on reverse side of PCB.)

Switch for 2nd valve is controlled by existing GPIO signal accessable on the flex circuit.

Ground for 2nd valve is accessable at the pressure sensor.

Existing Maybird electrical system, with modifications for the SASS prototype shown in BOLD lines.
TITLE: SASS_System_Wiring_Diagram
Document Number: REV: PR-1
Date: 10/13/17 7:45 PM   Sheet: 1/1

Figure 8 – Circuit diagram of the electrical components added for the backpack

d. *Control Algorithm Design:*

The adaptive control algorithm for controlling the vacuum level and step detection functions of the pump was developed and refined.

Recorded data sets from three previous patients were used to test the functionality of the control algorithm of the vacuum pump developed in the first year. When the data included exaggerated socket dynamics step and leak detection in the control algorithm was seen to be inaccurate. Two action items for improving the control algorithm were identified from these tests:

   I. Improve ability to differentiate between steps and pump cycles.
   II. Eliminate steps appearing as leaks (and causing pumping).

To address the first item a step is now detected by the signal exceeding the magnitude of a threshold parameter in the positive direction and then having a trough that dips below the negative magnitude of the step threshold parameter. After a step is detected at this trough, another step cannot be detected for a set timeout with a default of 0.625s, which limits step detection to a cadence of 1.6 Hz

or less. Both the threshold parameter and the minimum cadence timeout are adjustable parameter that can be set by the prosthetist for each patient. The algorithm also prevents step detection while a valve is operating and for the length of the timeout parameter after the valve stops. This reduces the number of false positives resulting from socket dynamics after pumping.

For leak detection, two additional low-pass exponential moving average filters were added at 0.1 Hz to slow the response of the system and capture changes to the average pressure. The new algorithm was applied to the recorded pressure data for normal and exaggerated socket dynamics and found to have accurate step and leak detection.

A preliminary volume element control algorithm was also developed. There are three main parts to the volume element control algorithm; the donning stage, the operational stage, and the doffing stage. In the donning stage the liner is evacuated before being donned by the user. The control algorithm will then begin attempting to evacuate the socket while the user dons the liner. When the socket is donned and a seal is made the pressure sensor in the pump will detect it and begin attempting to reach the socket target pressure. Once the target pressure is reached in the socket the system will switch back to the volume elements and allow them to expand then they will be pumped down to their target pressure. During operation the system will periodically switch from the socket to the volume elements and adjust them to their target pressure. The target pressure in the volume elements will be set to a target pressure, which will either be a fixed value or an offset from the socket pressure. To doff the liner the user will turn off the pump and wait for the liner to be evacuated.   Because of the number of unknown variables involved in the relationship between the air pressures and surface pressures in the system the final control algorithm for the volume elements will be heavily influenced by the results of the clinical trial. Using these results will also allow the algorithm to incorporate the user's perception of comfort. The simple algorithm described above with the addition of comprehensive data logging features and a few refinements will be used during the clinical trial.
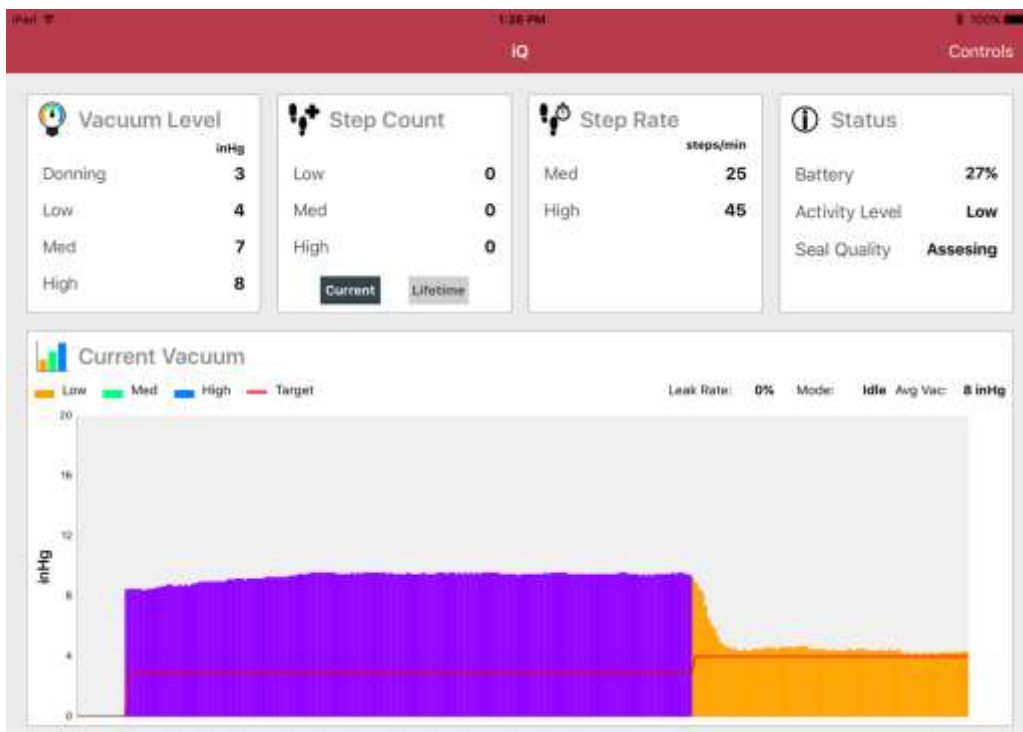
Figure 8 – A screen shot from the mobile software.

The Mobile software was also refined and step rate and seal status information was added to the UI. This software will allow users and prosthetists to interact with the liner pump system and adjust settings. The software also provides a realitime graph of the current pressure in the socket.

What opportunities for training and professional development has the project provided?

Nothing to Report.

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Assembly of what will hopefully be the final prototype will be completed and a final design review will be held. Once our team has approved the design the 15 systems required for the clinical trial will be manufactured. The control algorithm for the volume elements will be implemented and refined. Then the clinical trial will be conducted and the results will be analyzed. The results of the trial may be used to update the control algorithm.

4. **IMPACT:**

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

The project will improve living conditions for transtibial amputees.

5. **CHANGES/PROBLEMS:**

Changes in approach and reasons for change

As described in the discussion of results, the volume element to pump connection circuit has been updated from the original design. The medial and posterior elements are now connected so that the pump can be used to adjust them simultaneously. Their roles are still distinct and are biased on their shape and placement in the liner. The larger posterior element provides the majority of the volume adjustment while the smaller vertical medial element provides stability but their relationship to limb volume is similar enough that it makes sense to link the control of these two elements. The distal element however, primarily provides stability and comfort and has a somewhat inverse relationship with limb volume compared to the other volume elements. It is now linked to the socket volume. These design changes were necessary maintain the simplicity and usability of the system.

Actual or anticipated problems or delays and actions or plans to resolve them

There have been delays in the approval process for the clinical trials. We were initially planning to work with two VA hospitals in Florida which both had their own internal review boards with site-specific documentation and applications. However, the one of the sites was under review and was not able to be included in the trial so the application process was restarted with a single VA hospital, which is overseen by the IRB board at the University of Florida. This problem has been resolved and there are no other anticipated delays.

Changes that had a significant impact on expenditures

Due to delays in IRB approval expenditures related to the clinical trial such as travel and the fabrication of test systems for the participants have not yet been made. Consequently we are significantly under budget. We have applied for and received a no cost extension of one year for the project. During which time the trial will be conducted.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

6. **PRODUCTS:**

Nothing to Report

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

What individuals have worked on the project?

Name:	David Boone, PhD
Project Role:	Principal Investigator
Research Identifier:	0000-0002-9479-8396
Nearest person month worked:	4
Contribution to Project:	No Change
Name:	Lucas Lincoln

Project Role: Technical Supervisor
Research Identifier: 0000-0002-7139-0267
Nearest person month worked: 0
Contribution to Project: No Change

Name: Aaron Griswold
Project Role: Project manager
Research Identifier: 0000-0002-5154-2315
Nearest person month worked: 2
Contribution to Project: No Change

Name: Courtney Fisher
Project Role: Mechanical Engineer
Research Identifier: 0000-0003-4315-3835
Nearest person month worked: 3
Contribution to Project: No Change

Name: Ray Austin
Project Role: Electrical Engineer
Research Identifier: 0000-0002-0586-9966
Nearest person month worked: 1
Contribution to Project: No Change

Name: Jonathan Maier
Project Role: Software/Firmware
Research Identifier: 0000-0002-2895-6632
Nearest person month worked: 2
Contribution to Project: No Change

Name: Jung Kim
Project Role: Software/Firmware
Research Identifier: 0000-0001-7887-6879
Nearest person month worked: 2
Contribution to Project: No Change

Name: Aizen Ulric
Project Role: Materials Engineer
Research Identifier: 0000-0002-8133-4541
Nearest person month worked: 7
Contribution to Project: No Change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Organization Name: Cadence Biomedical

Location of Organization: Seattle, WA

Partner's contribution to the project *(identify one or more)*

Collaboration Staff exchanged knowledge and tools for liner manufacturing.

8.   **SPECIAL REPORTING REQUIREMENTS**

QUAD CHARTS:

Smart Adaptive Socket for lower extremity prosthetic users

Log Number: OR140328
Award Number: W81XWH-15-1-0712

PI: Boone, David   **Org:** Orthocare Innovations   **Award Amount:** $747,345

Product Development Aims
- Refine viscoelastic interface liner for manufacturability
- Optimize and validate hardware
- Validate control algorithm integrating force data for optimal fit
- Determine number of elements with user feedback
- Develop smart phone App to enable user control of parameters

Approach
We propose to develop a Smart Adaptive Socket that will dynamically adapt contact pressure on the residual limb to ensure a superior fit with high performance when needed, and will modulate pressure for periods of comfort during rest. The pressure within 8 viscoelastic vacuum elements will be modulated using a silent pump with force and pressure sensing input and a dynamic control algorithm. User control with smart phone App.

Total volume and volume distribution adjusting viscoelastic interface liner

Modular, integrated viscoelastic vacuum elements(99%)

Mechanical efficiency of interface loading monitored in real-time(75%)

Silent HVLP Smart Pump(98%)

We have developed a silent, high volume low pressure (HVLP) pump to modulate interface shape. We have developed, marketed and published 9 peer-reviewed publications validating our load sensing element

Timeline and Cost

Activities CY	15	16	17
Refine Viscoelastic Interface			
Define vacuum element locations			
Validate Hardware software and controls			
User testing of Smart Adaptive Socket			
Estimated Budget ($K)	$94	$374	$279

Updated: 9/30/17

Goals/Milestones (Example)

CY15 Goal – Complete system specifications
☑ Refine material engineering of interface
☑ Bench test functionality
☑ Initiate prototyping of smart pump and control system
CY16 Goals – Systems Integration
☑ Design and Produce prototype adaptive viscoelastic liners
☑ Design and Produce prototype smart pump control system
CY17 Goal – Patient testing
☐ Field test on amputee subjects
Comments/Challenges/Issues/Concerns
- To enhance future manufacturability of the technology we engaged the help of an existing prosthetic liner manufacturer for fabrication of prototypes.

Budget Expenditure to Date
Projected Expenditure: $747,345
Actual Expenditure: $572,694